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H4J JCE J30X J31J
U1S S1032

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WO 91/14401 A1 US 5279546 A US 4856529 A

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INT CL^6 A61B 8/12 17/22 17/32 17/36 , A61N 7/00
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(54) Ultrasonic visualisation catheters

(57) A balloon catheter including an ultrasonic transducer at its distal end, is disclosed. The acoustic tip may include the following components bonded to a flexible polyimide substrate on the outer surface of a inner catheter body: a micromachined PZT ultrasonic transducer array; which may include, 4 multiplexer integrated circuit chips; and a fourteen-way interconnect ribbon. A hole along the axis of the inner catheter body enables a guide wire to be passed the length of the distal portion of the catheter. Also disclosed are a sheath catheter with a coaxial transducer/multiplexer array, and a guide wire catheter with a distally mounted transducer array.

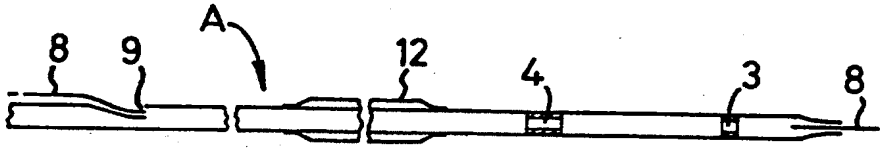

FIG.5

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At least one drawing originally filed was informal and the print reproduced here is taken from a later filed formal copy.

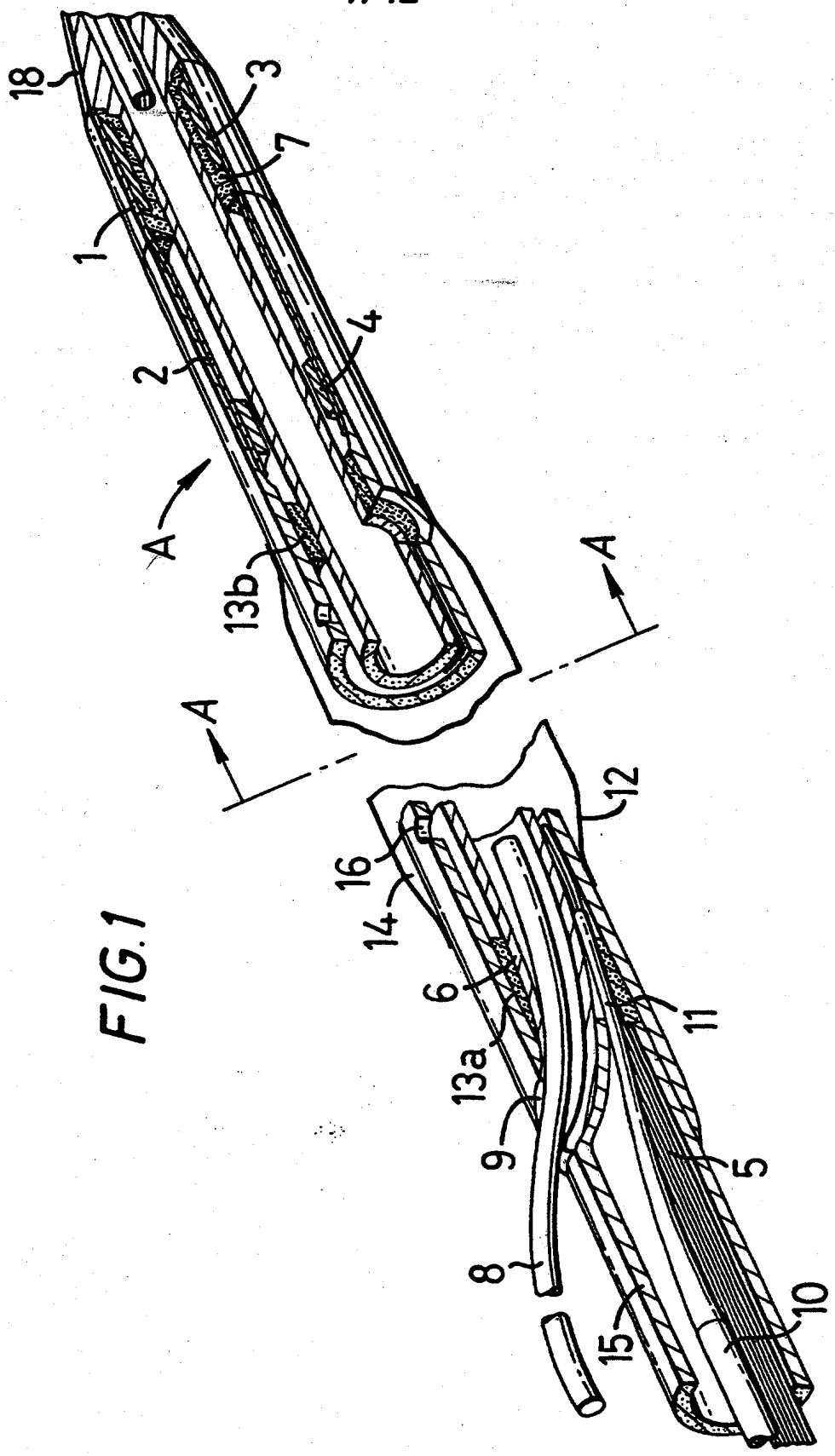


FIG.1

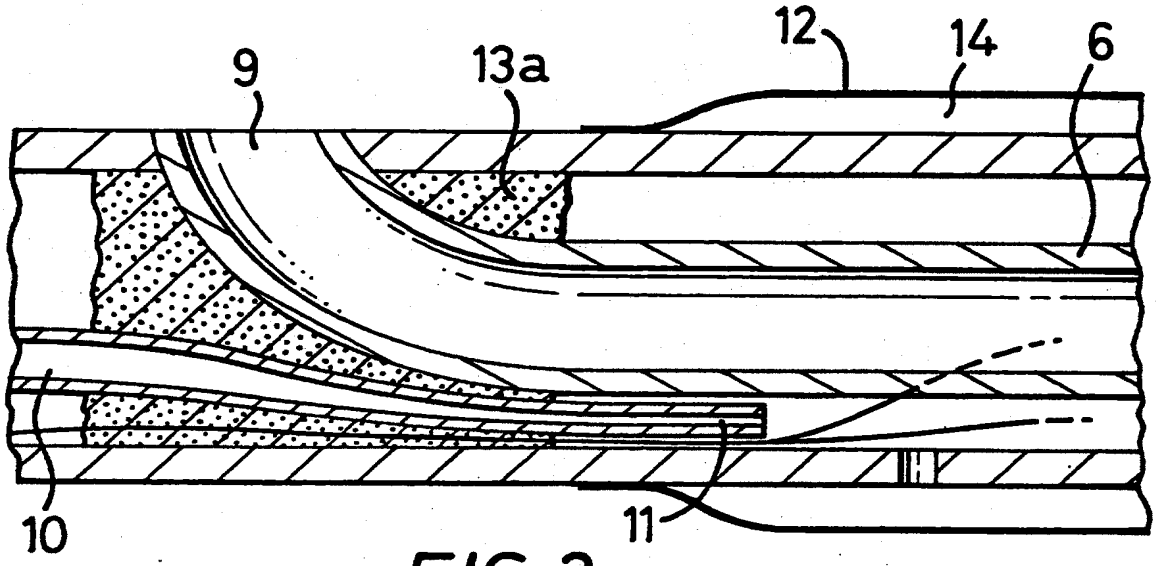


FIG. 2

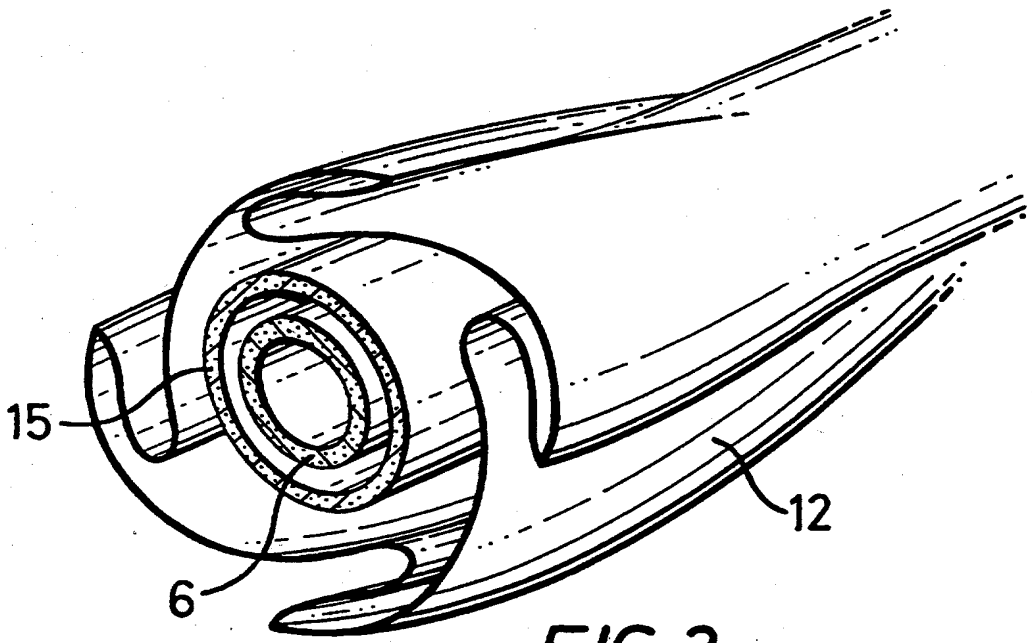


FIG. 3

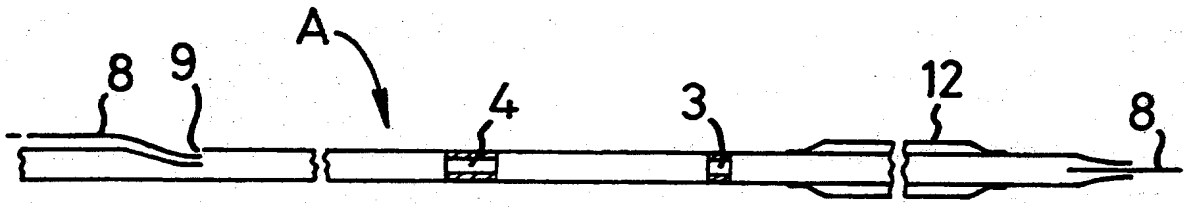


FIG. 4

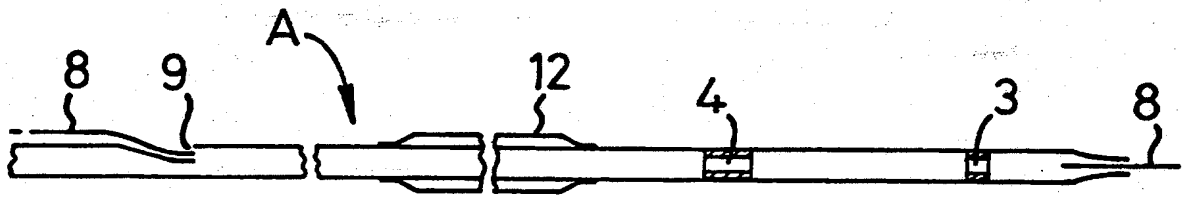


FIG. 5

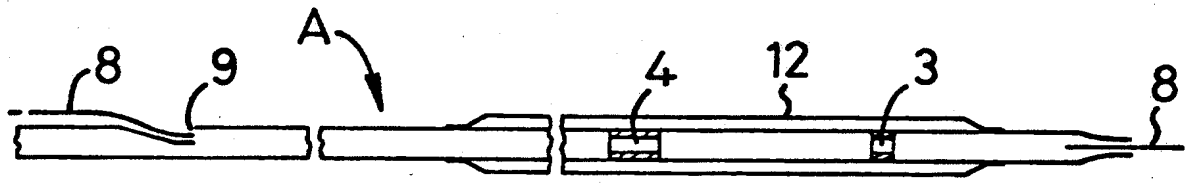


FIG. 6

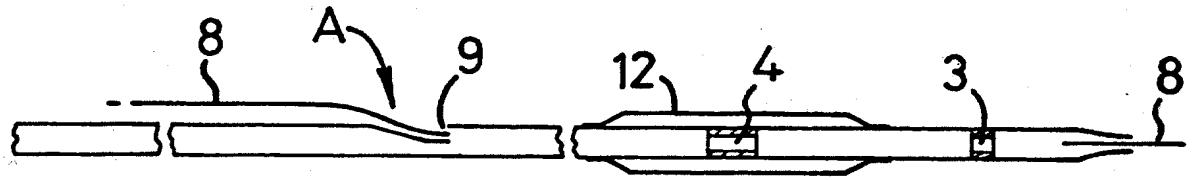


FIG. 7

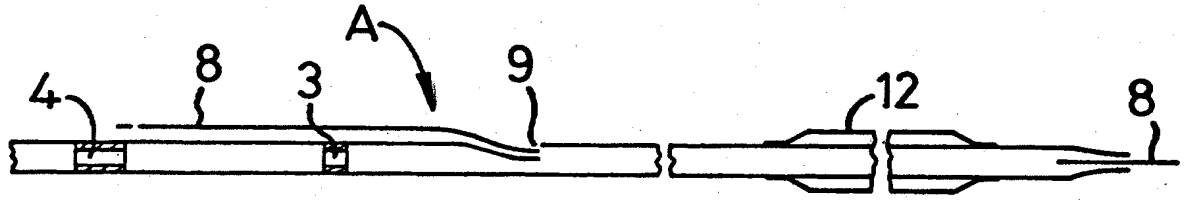


FIG. 8

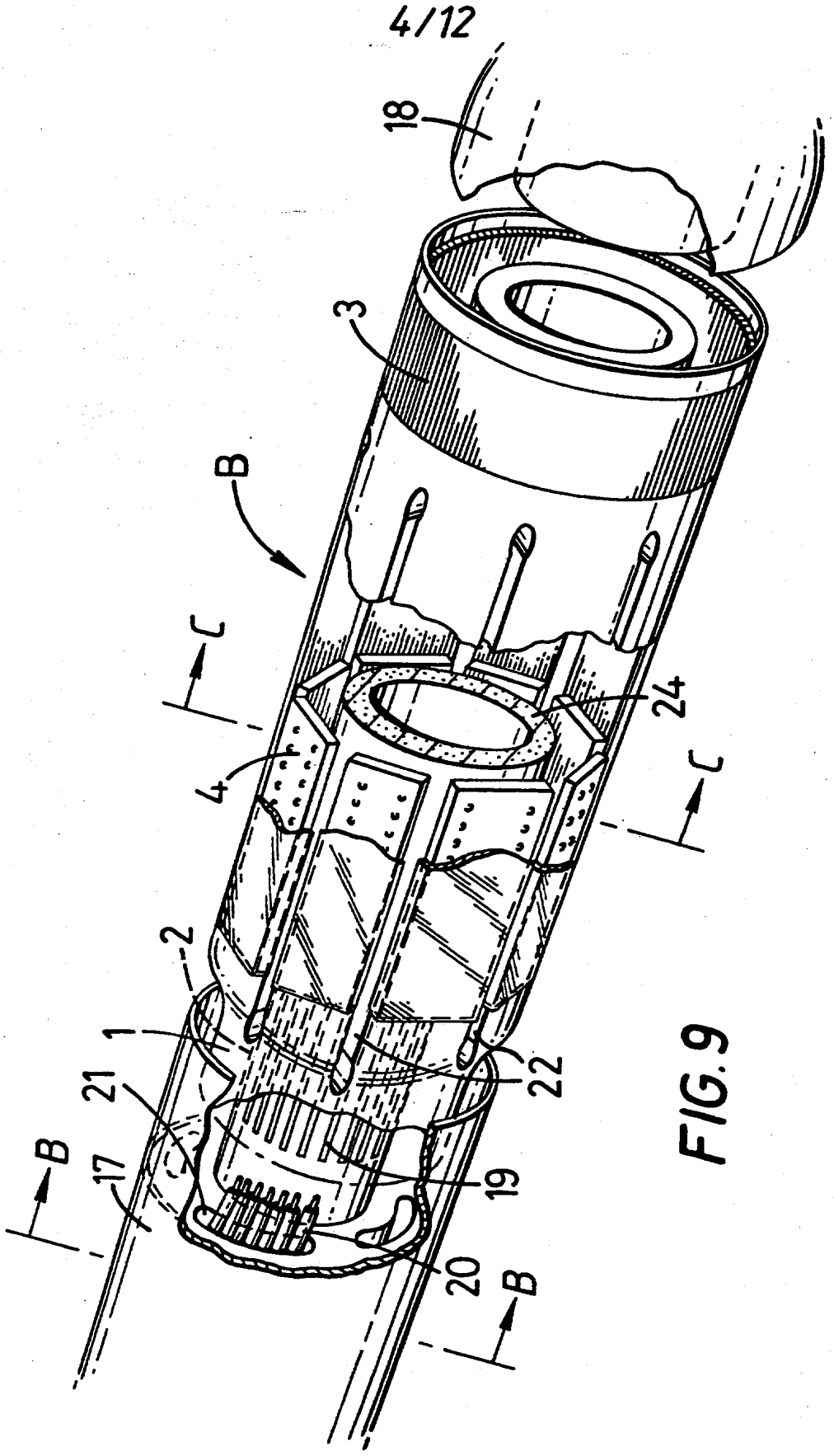


FIG.9

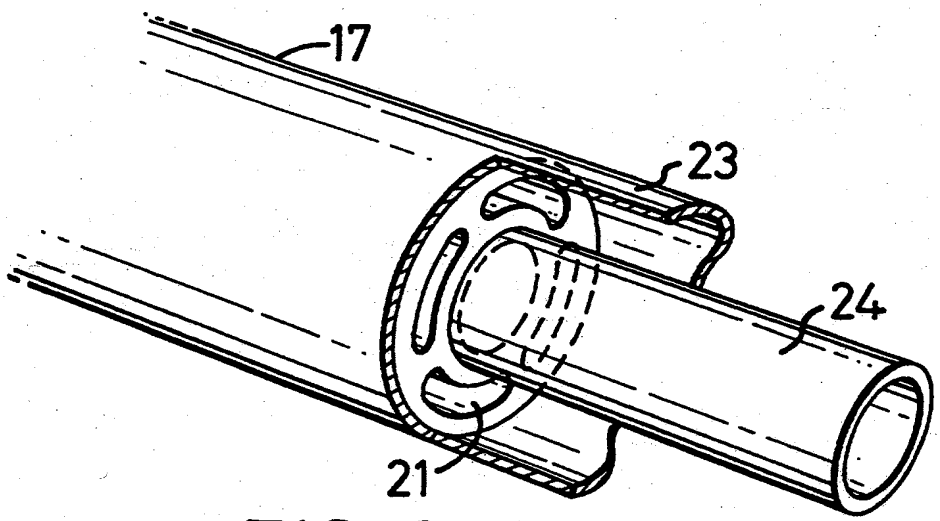


FIG.10

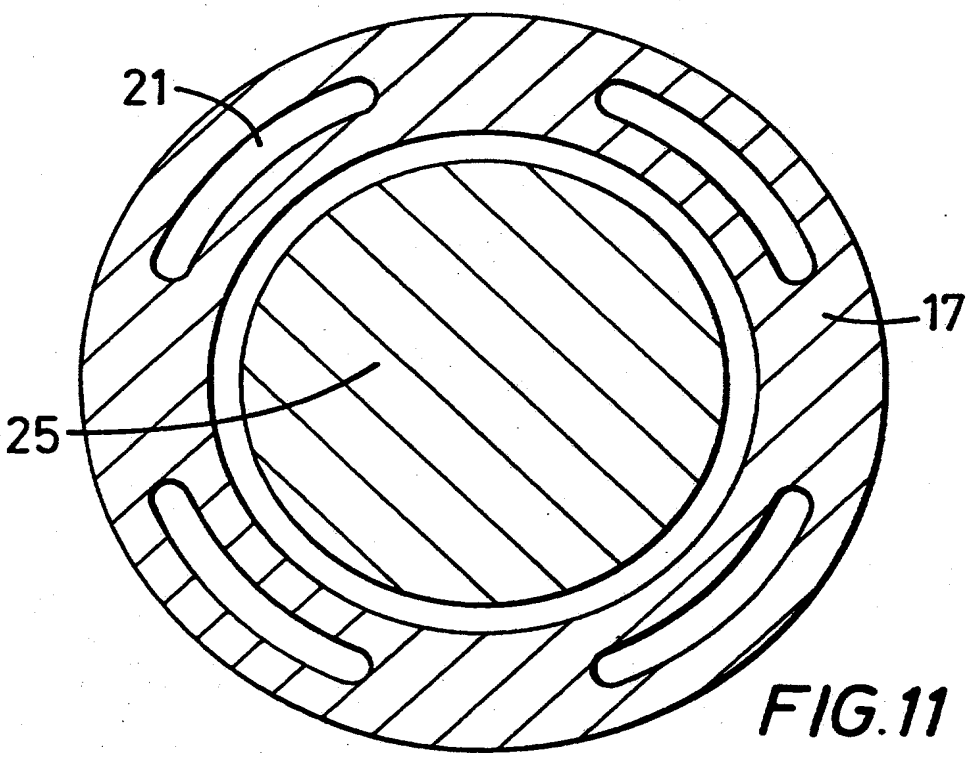


FIG.11

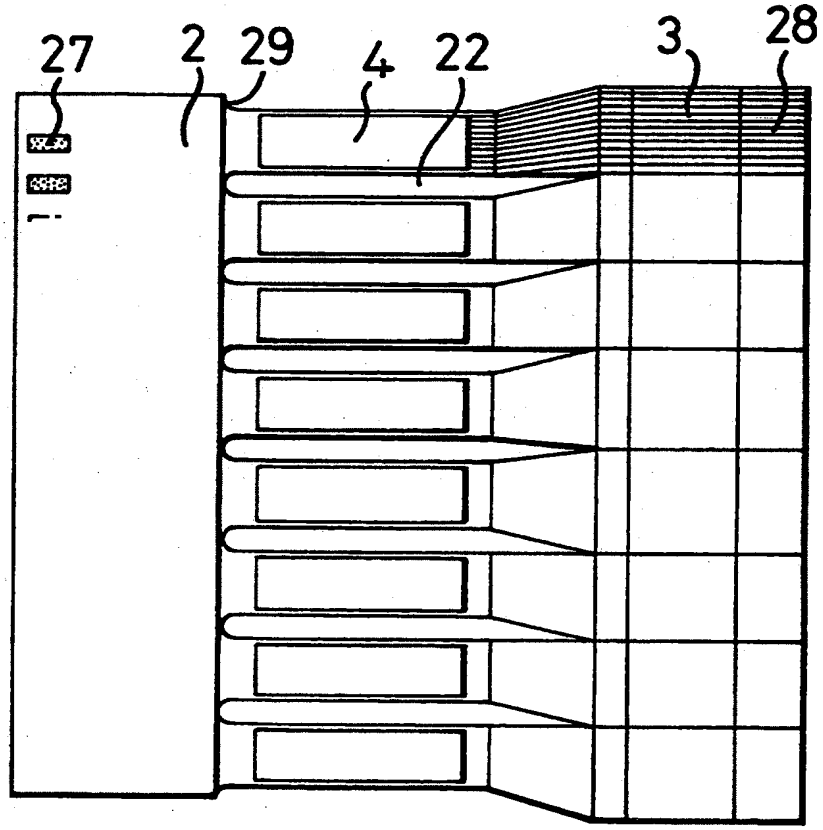


FIG.12

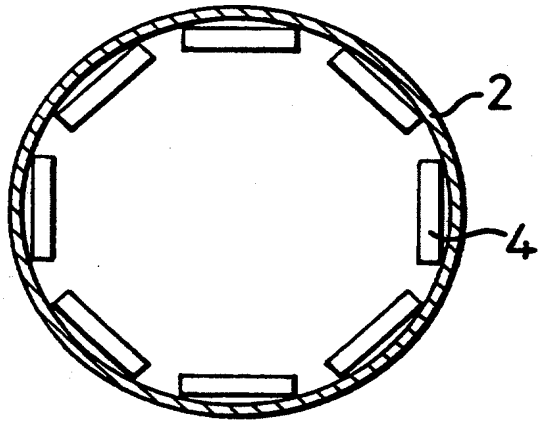


FIG.13

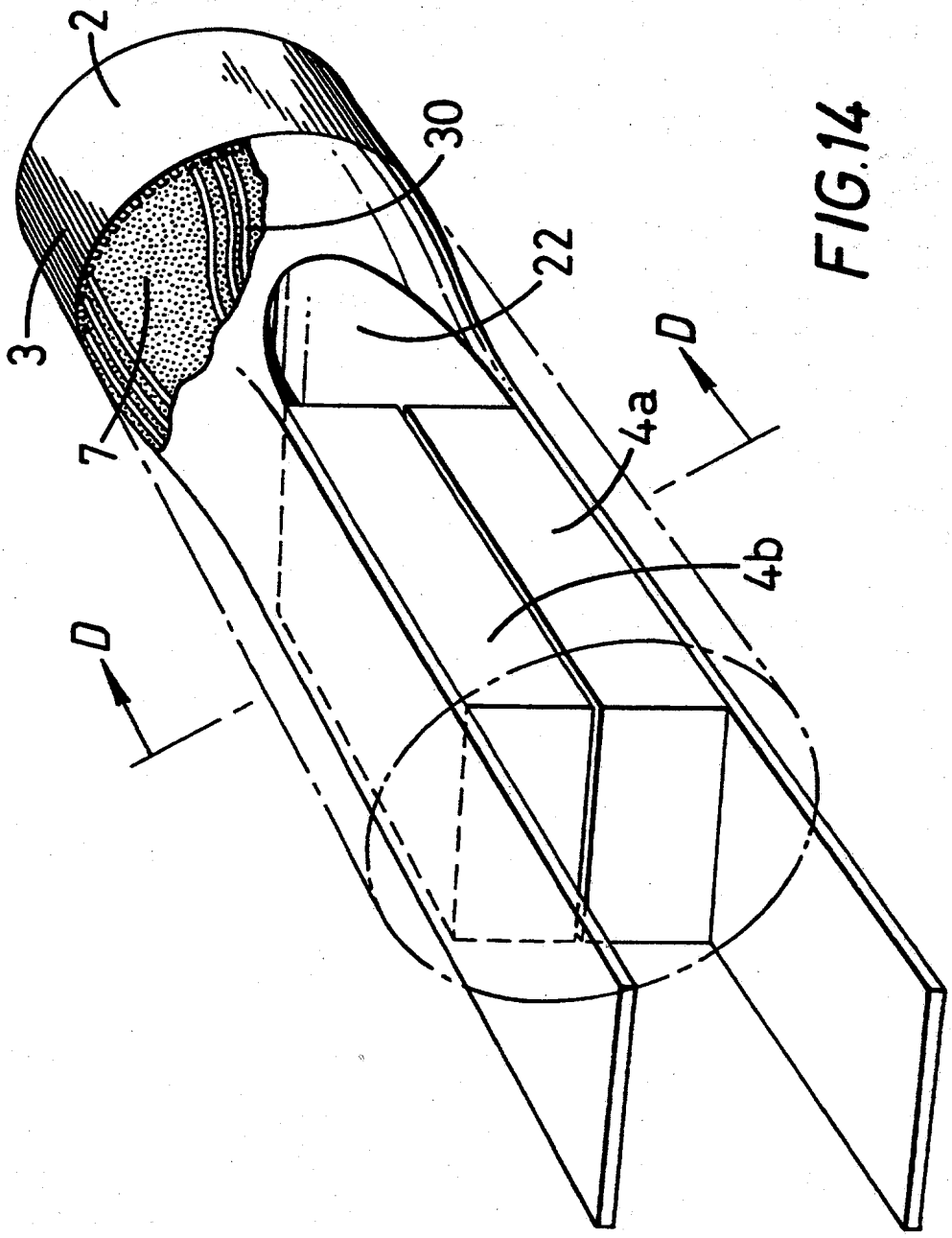


FIG.14

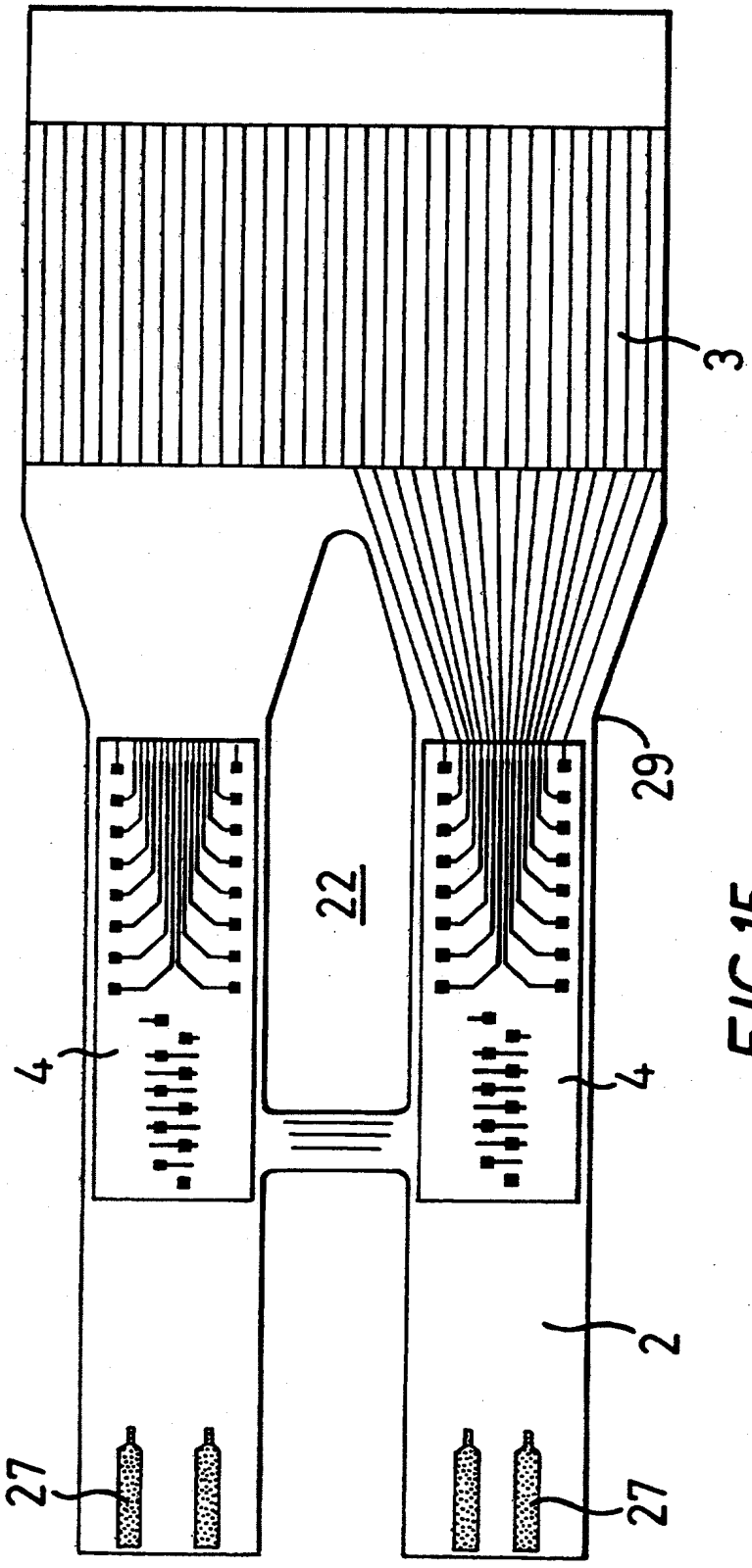


FIG.15

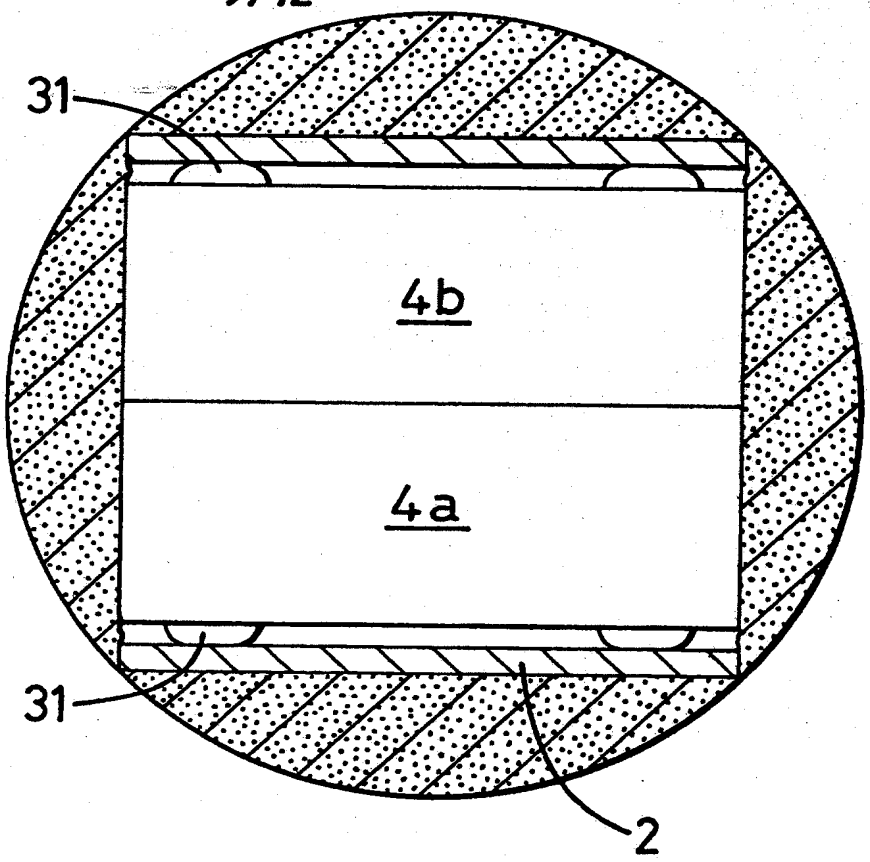


FIG.16

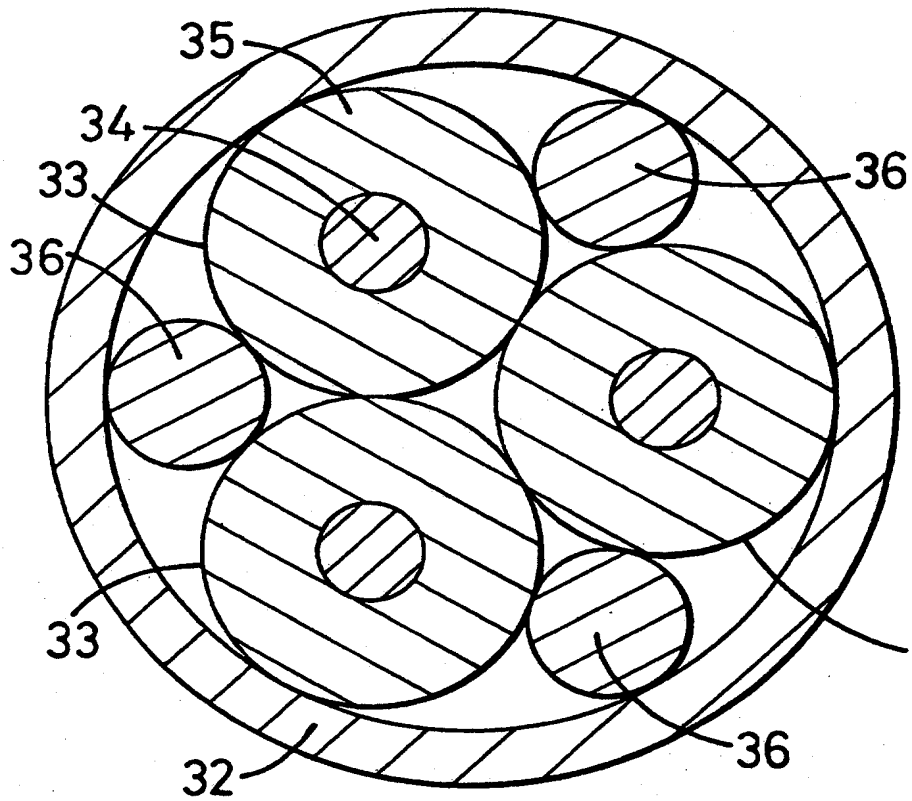


FIG.17

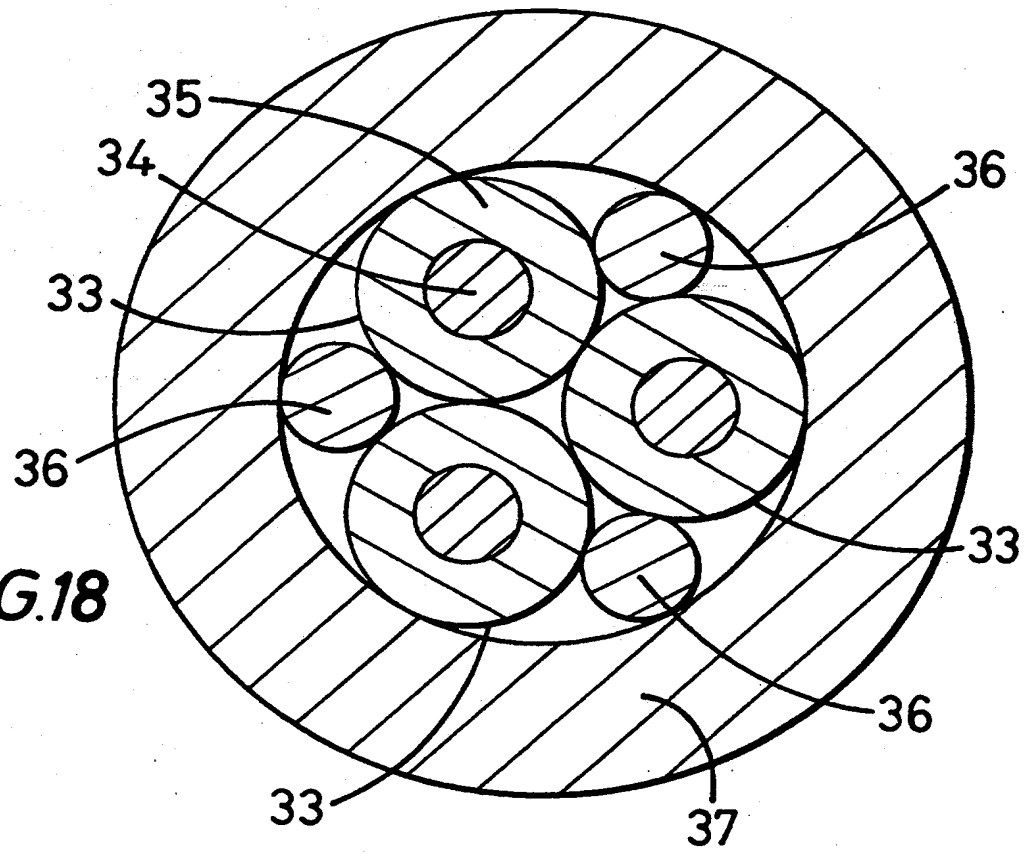


FIG.18

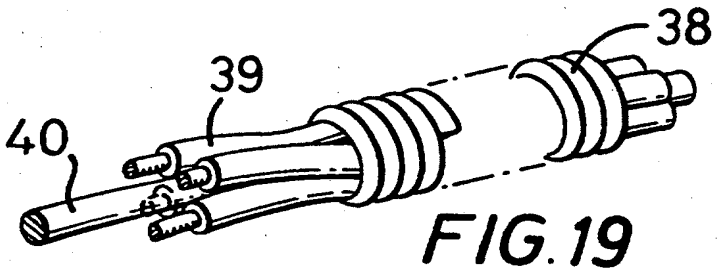


FIG.19

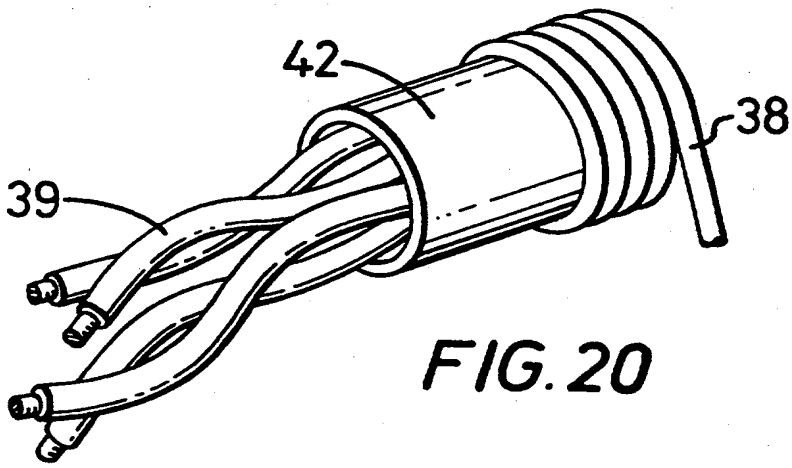
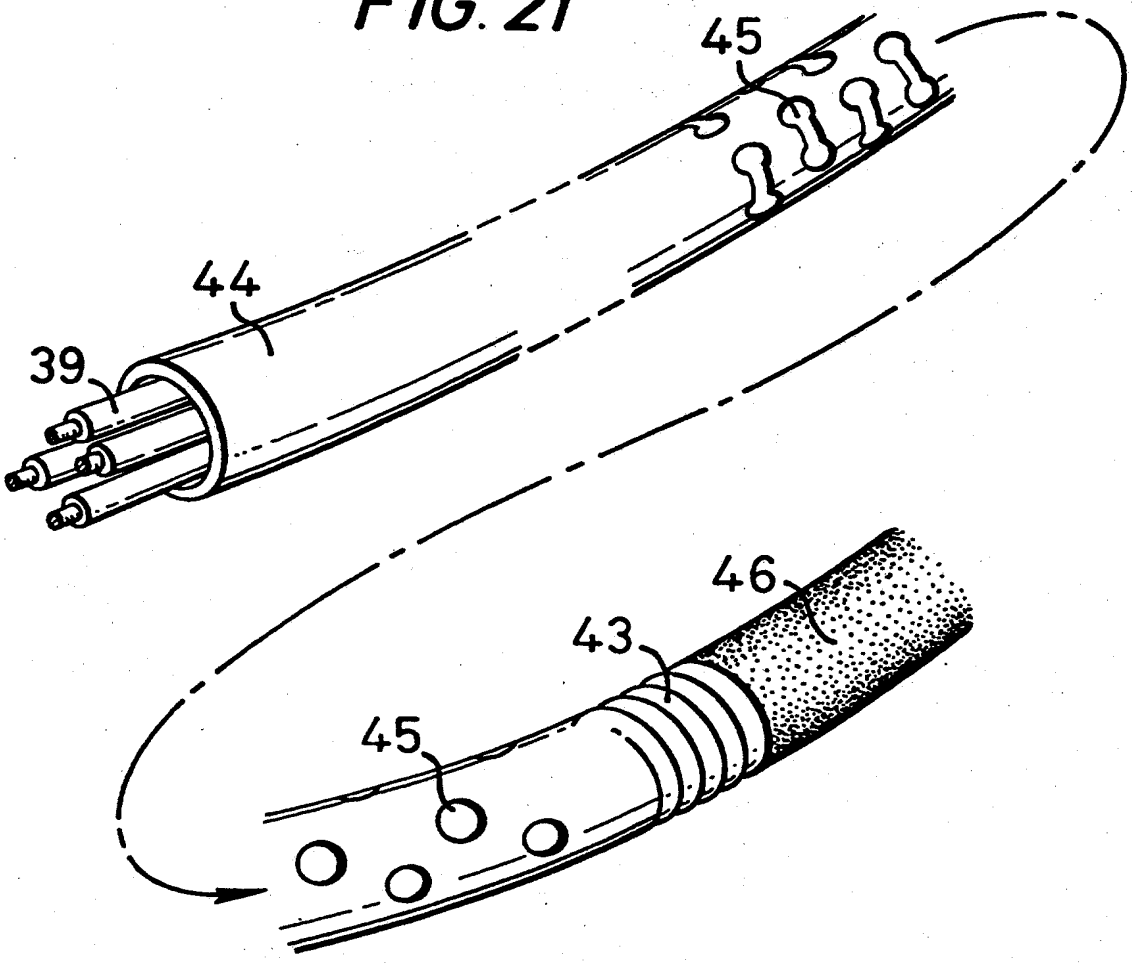


FIG.20

FIG. 21



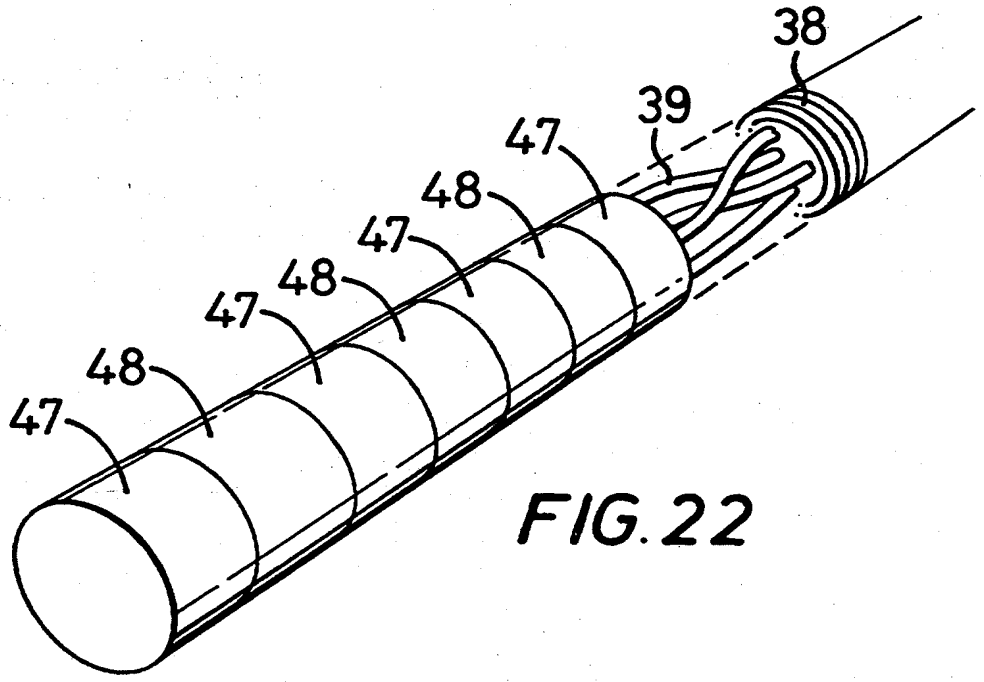


FIG. 22

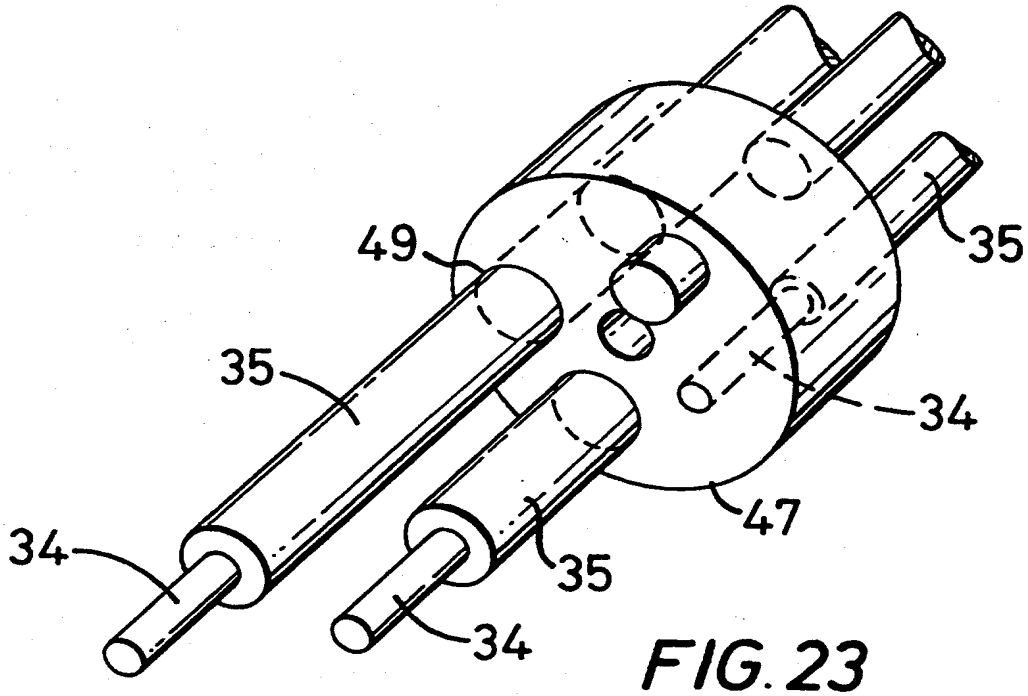


FIG. 23

ULTRASONIC VISUALISATION AND CATHETERS THEREFOR

The present invention relates to ultrasonic visualisation and catheters therefor.

The present invention relates generally to the field of ultrasonic imaging, intravascular ultrasound imaging or IVUS in transluminal coronary angioplasty known as PCTA.

In a previously proposed 5 French IVUS device having an annular array of piezo-electronic transducers at its distal end, the array which could comprise sixty-four transducer elements, being about 1.6mm in diameter. In this arrangement the transducer elements were excited in pairs thus necessitating thirty two interconnections and, given the size of the catheter outer body, it was possible to route four eight-way ribbon cables within it.

When designing such a catheter with dimensions less than 5 French, problems relating to the greatly reduced diameter and thus available space for interconnections are encountered. Excitation signals from an external separate apparatus are routed through a small number of interconnections (for example ten) to individual transducer elements through the use of flip-chip-bonded multiplexers positioned at the distal end of the catheter and proximally to the transducer array. A method of manufacturing the transducer array and associated multiplexers is disclosed in our copending published UK Patent Application No. 2,287,375 (which is hereby incorporated by reference) in which the assembly is first formed in the flat and then wrapped into a substantially cylindrical configuration. More particularly, the flat assembly comprises the transducer array, the

multiplexer chips, electrically conducting leads and a suitable matching layer. The use of the multiplexer chips which act as electronic switches permits the use of fewer interconnections which can thus fit into a smaller lumen.

In conventional PCTA an incision is made in the femoral region of the patient's leg to introduce a mid-length sheath having a diameter of typically 8 French or 2.66 mm into the femoral artery. A much thinner guide wire (typically 0.014 inches or 0.356mm diameter) is then introduced via the resulting opening and is manually guided right up to the exact location of the affected region. The affected regions of the coronary arteries follow a tortuous route and the cardiologist relies upon the rigidity of this wire to guide it into place.

Once the end of the guide wire arrives at the required location it is kept firmly in place and in current PCTA/IVUS applications the cardiologist next has to go through an involved procedure of inserting further guide catheters, or sheath catheters prior to finally introducing the IVUS or other treatment catheter. .

Keeping the guide wire firmly fixed, a guide catheter of similar dimensions to the mid-length sheath is then inserted over the guide wire, the mid-length sheath still being in place and manually guided through the opening of the aorta stopping a short distance into the coronary artery. There are various versions of guide catheters which usually have the distal ends gently curved or looped depending upon their ultimate destination within the artery system. Contrast opaque dye is then pumped through the guide catheter to flush through the aortic system rendering the cardiac vessels visible on the fluoroscope monitor to enable the cardiologist to visualise the situation.

The device catheter has a central lumen whose diameter is slightly larger (typically 0.017 inches or 0.43 mm) than that of the guide wire. This time, keeping the guide-wire/guide-catheter assembly firmly in place, the device catheter is fed over the guide wire and is simply pushed up the guide wire through the guide catheter..

The progress is monitored by noting the location of an X-ray opaque marker on the moving device catheter relative to the X-ray opaque marker on the fixed guide catheter. When the two markers are coincident the cardiologist knows that the calcified region of interest has been reached. If a balloon catheter is being used saline solution may now be pumped into the balloon to inflate it thereby dilating the affected artery. The results of the procedure are then examined using the imaging device.

The disadvantage of this known system is the inconvenience of having to withdraw one catheter and insert another in order to swap between the PCTA or other treatment procedure and the imaging procedure.

The flexible transducer design permits the possibility of mounting radially thin ultrasound arrays onto catheter configurations that can be used to simplify the swapping between procedures, and the present invention is concerned with these catheter configurations..

A first aspect of the present invention relates to the design and manufacture of a catheter which has both a wrapped acoustic tip according to our UK Patent Application 2,287,375 and an angioplasty balloon..

A second aspect of the present invention relates to the manufacture of a 5-6French or a 8-9French sheath catheter having a wrapped acoustic tip (according to our UK Patent Application No 2,287,375) within its body. The resultant combined sheath and transducer array catheter may be used in conjunction with current commercially available 2.9French or 5.0French balloon catheters respectively for angioplasty and stent delivery purposes or with atherectomy devices such as a Rotoblator (Registered Trade Mark) which could be inserted into the sheath catheter of the present invention.

A third aspect of the present invention relates to the combination of a wrapped acoustic fixed array transducer mounted on a guide wire which could be 0.014 inches in diameter to provide a 1 French catheter to produce what may be referred to as a guide-wire catheter. One key feature of this third aspect of the present invention is the manner in which the 0.014 inch dimension is maintained throughout the entire length of the catheter thus permitting device interchange during PCTA procedures with minimal disruption. The invention also reduces the number of electrical interconnections which in the specific embodiment are four.

How the invention may be carried out will now be described by way of example only and with reference to the accompanying drawings in which:

Figure 1 is a perspective, fragmentary cut-away view of the distal end of a catheter assembly of one embodiment according to a first aspect of the invention;

Figure 2 is a longitudinal fragmentary sectional view of part of the assembly shown in Figure 1;

Figure 3 is a fragmentary sectional perspective view taken on the line A-A of Figure 1 and showing the balloon element of the catheter assembly shown;

Figures 4 to 8 are simplified diagramatic representations of possible configurations for the type of combined catheter assembly shown in Figures 1 to 3;

Figure 9 is a perspective fragmentary part cut-away view of one embodiment of a catheter assembly constructed according to a second aspect of the present invention.;

Figure 10 is a detail of Figure 9 but only showing the relationship between the sheath catheter and the multiplexer sheath;

Figure 11 is a cross-sectional view taken on the line B-B of Figure 9, but also showing the device catheter;

Figure 12 is a view showing the transducer array and associated multiplexers in the flat condition;

Figure 13 is a cross-sectional view taken on the line C-C of Figure 9;

Figure 14 is a fragmentary perspective view of one embodiment of the third aspect of the present invention;

Figure 15 illustrates the ultrasonic transducer array and associated multiplexer arrangement of Figure 14 when in the flat configuration;

Figure 16 is a cross-section taken on the line D-D of Figure 14;

Figures 17 to 21 illustrate cross-sectional and perspective views of a number of body and interconnect configurations to the distal end of which the arrangement of Figure 14 is attached.

Figures 22 and 23 illustrate an arrangement by which the electrical connections to and from the ultrasonic transducer array and multiplexer arrangement are accomodated at the

proximal end of the catheter, and how the 1 French dimension is not exceeded by the proximal connector itself.

Figures 1 to 3

The distal end of a catheter assembly is generally indicated at A in Figure 1. The catheter has an acoustic tip 1 consisting of three major components 3, 4, 5 bonded onto a flexible polyimide substrate 2. These components comprise a micromachined PZT ultrasonic transducer array 3, four multiplexers in the form of integrated circuit chips 4 and a fourteen-way interconnect ribbon 5.

The acoustic tip 1 was originally formed in the flat and then wrapped into the form shown by the method disclosed in our published UK Patent Application No. 2,287,375. It is then mounted onto that part of the catheter referred to as inner body 6. An acoustic backing material layer 7 separates 1 and 6.

A guide-wire 8 enters the catheter through the entrance of 9 the catheter inner body 6. The guide wire 8 is fairly rigid and when inserted into the inner body entry point 9 there is a potential for both the tip of the wire and the catheter outer body to kink. For this reason a stiffening tube 10 is provided to create an opposing and restoring force for the guide wire 8 thus maintaining the linearity of the device catheter.

The hollow stiffening tube 10 has a tapered distal end 11 and serves the dual purpose of acting as a supporting member for the guide-wire 8 and also as a lumen through which the saline solution may be pumped for inflation of a balloon 12 which is mounted on and around the catheter outer body 15.

The various components of the catheter assembly are so fused and sealed at two locations 13a and 13b that the saline solution is confined within a chamber 14 defined by the

catheter inner body 6 and the outer body 15 of the catheter. The saline solution is fed first through the stiffening tube 10 into the chamber 14 and finally through a number of balloon inflation holes 16 formed on the outer body 15 of the catheter and into the balloon cavity 14 thus inflating the balloon 12.

Figure 2 shows a detailed longitudinal fragmentary section at the inner body entry point 9 and Figure 3 shows how the balloon 12 is folded in its retracted condition..

The problem previously discussed in connection with the known so-called over-the-wire procedure is overcome by the use of the above-described catheter inner body 6 which consists of a short length of catheter body suitably shaped and fused into the short section of the outer body 15 of the device catheter.

The resulting cross section over the last short distal length of the catheter is that of a double-lumen structure. The advantage is that the guide wire is inside the array but only inside a short section of the rest of the catheter, facilitating exchange, as in known so-called 'rapid exchange catheters'. In the catheter according to the present invention the device catheter is fed onto the guide wire 8 through the side-entry aperture 9.

In the embodiment shown in Figures 1 to 3 the dimensions of the various elements of the catheter are as follows:

Balloon 12: 3.5F (1.17 mm outside diameter)

Catheter inner body 6: outside diameter 0.55mm; inside diameter 0..430mm

Guide wire 8: diameter 0.014 inches (0.356mm);

Catheter outer body 15: outside diameter 2.9F (0.97mm)

Tapered tube 11: outside diameter 0.30mm; inside diameter 0.15mm.

Figures 4 to 8

Figures 4 to 8 are diagrammatic illustrations of various possible embodiments in which Figure 5 represents the arrangement shown in Figures 1 to 3

In all these embodiments the slotted piezo-ceramic array 3 and the multiplexer chips 4 are shown mounted inside the outer body 15 of the catheter A with a balloon 12 mounted on the outside of it. The guide-wire 8 is shown entering the catheter via the inner body entry point 9.

In Figure 4 the balloon 12 is positioned distal or downstream with respect to the transducer array 3 and the multiplexer arrangement 4. With this arrangement in order to get the saline solution into the balloon in the position shown it would have to be passed through the multiplexer 4 and the array 3 which could be disadvantageous given the overall dimensional restrictions. A further disadvantage is the possibility of distortion of the array by the pressure of the inflation fluid.

As indicated earlier Figure 5 is equivalent to Figure 1 and illustrates an embodiment where the balloon 12 is positioned between the multiplexer chips 4 and the inner body entry point 9. This is the preferred embodiment because the balloon is proximal to both the multiplexer 4 and the array 3 and they are all distal with respect to the inner body entry point 9. The balloon 12 may thus be inflated without disturbing the array 3. In addition the array 3 can have a smaller diameter than the balloon profile 12.

Figure 6 illustrates an embodiment where the balloon 12 envelopes the transducer array 3, and the multiplexer chips 4. Possible array distortion during balloon inflation, and the attenuation of the ultrasound by the balloon make this a less optimal configuration.

Figure 7 illustrates an embodiment in which the key feature is that the balloon covers the mux section which is separated axially from the array without enclosing the array.

Figure 8 illustrates an embodiment where both the balloon 12 and the inner body entry point 9 are positioned distally with respect to the transducer array 3 and multiplexer 4.

Figures 9 to 13.

These figures illustrate an embodiment of a second aspect of the present invention.

A catheter generally indicated at B comprises a sheath catheter body 17 which carries at its distal end a cylindrical ultrasonic transducer array 3 and associated multiplexer arrangement 4, the latter being manufactured by the method disclosed in our published UK Patent Application No. 2,287,375.

Figure 9 is a view of the entire final distal assembly and it shows a flexible metallised polyimide substrate 2 with electrically conducting tracks 19 defined on one of its surfaces. Eight integrated circuits 4 forming a multiplexer arrangement are bonded onto pads defined on the substrate 2. Excited transmitted and received signals are conveyed from

external electronics to and from individual sets of elements of the transducer array through four sets of miniature ribbon cables 20 fed right through the sheath catheter via four lumens 21 created within the walls of the sheath catheter 17.

There are stress relief slots 22 cut into the polyimide substrate 2 to aid in the wrapping process. The assembly is completed by the use of a soft tip 18 that enables a smooth entry into the coronary arteries to be made. The elements of the array 3 comprise precision diced piezo electric ceramic such as PZT.

Figure 10 illustrates an outer sheath 23 which encapsulates for the multiplexer integrated circuit chips 4. A tubular body extension 24 with an inner bore of 4F is also provided and serves the dual purpose of acting as a rigid former for the fragile circuitry of the multiplexer section and as a conduit through which the device catheter (not shown) can be inserted.

.Figure 11 illustrates the dimensional compatibility between a sheath array catheter 17 and device catheter 25 - which typically could be a balloon catheter or artherectomy device. The four thin lumens 21 extend through the entire length of the sheath catheter 17 to the imaging and processing electronics and are designed to accomodate the four ribbon cables 20 railed from the array assembly. The sheath catheter 17 could be 5-6 French with the device catheter 2.9 French. Alternatively the sheath catheter could be 8-9 French and the device catheter 5.0 French. As indicated earlier the method of manufacturing the transducer array and multiplexer arrangement is substantially as disclosed in our published UK Patent Application No. 2,287,275. In that method the transducer array and multiplexer arrangement are first fabricated in a flat configuration as shown in Figure 12.

Figure 12 illustrates the flexible polyimide substrate 2 that has been metallised on both faces and has bonded to it a thin rectangular plate of piezo-ceramic material 3 such as PZT and eight integrated circuit chips 4 comprising a multiplexer arrangement. The multi-conductor ribbon cable 20 is not shown in Figure 12 but is bonded onto the interconnect bond pads 27. The thin rectangular piece of piezo-ceramic material is precision diced into one hundred and twenty eight elements. There is a rectangular piece of graphite 28 that provides part of an electrical ground path. The sides of the substrate 2 are formed with a certain profile 29 which is determined by the final wrapped diameter. There are seven stress-relief slots 22 that aid in the wrapping process by making the substrate easier to form into a cylinder.

Figure 13 shows a cross section of the wrapped assembly. This cross sectional diagram shows the relationship between the eight integrated circuit chips 4 and the resultant surrounding cylinder of polyimide substrate 2.

Figures 14 to 16

These figures illustrate an embodiment of the third aspect of the present invention which comprises a 1 French diameter catheter and an associated cylindrical ultrasonic transducer array 3 with a multiplexer arrangement 4.

The multiplexer arrangement differs in configuration from that of Figures 1 and 9 in that it comprises two multiplexer chips 4 which are so positioned on a flexible circuit assembly 2 (see Figure 15) that when that assembly is rolled up, become positioned

back-to-back with the transducer array rolled into a cylindrical configuration. The entire assembly has an outside diameter no greater than 1 French (i.e. 0.014 inches). Such a device is of the same diameter as a typical catheter guide wire and thus would not only be able to access the thinnest of coronary arteries, but due to the use of on-board miniature integrated circuit switches 4, few electrical wires are involved thus keeping the body construction simple.

This leads to a low cost, single-use device. Additionally, there is no need for a lumen through the centre of this device. This resulting saving in space is now available for more acoustic backing layer for the transducer array than in other designs. This thicker backing layer results in a stronger and clearer signal being generated by the transducer array which, in turn, leads to a sharper and clearer image after employing suitable image processing.

Typically guide wires are not simple wires but are complex structures often consisting of two or more wires wound into a helix. Therefore although there is no discrete body, the term 'body' here refers to the whole assembly.

The backing layer is an ultrasound material combining high acoustic attenuation with defined acoustic impedance, consisting of a rubberised resin loaded with a suitable filler material such as tungsten powder, and is a cylinder of diameter of 0.24mm.

The device illustrated in Figure 14 would operate at 40 MHz and have thirty two transducer elements.

Apart from the use of only two multiplexer integrated circuits 4, instead of the eight of the embodiment shown in Figure 9, the general construction of the transducer array and associated multiplexers is substantially the same and manufactured by the general method discussed in our published UK Patent Application No. 2,287,375.

Figure 14 shows the distal end of the guide wire catheter which has mounted on it the acoustic transducer array and associated electronics and which has a dimension of 1 F. The two multiplexers 4a and 4b are flip-chip-bonded onto fine-pitch circuitry 30 defined on the flat metallised polyimide substrate 2 are shown. As indicated earlier the flexible film has been folded in such a manner so as to bring the two chips 4a 4b in contact with and positioned back-to-back with respect to each other. The transducer array 3 is also shown in its wrapped configuration the backing material 7 injected into the volume bordered by the inner diameter of the array. Also shown on this view is one of two stress relief slots 22 cut into the polyimide material that acts to aid in the wrapping process. There are electrical interconnections which run the whole length of the catheter and are bonded onto the bond pads 27 created on the flexible circuit.

Figure 15 shows the earlier stage in the manufacture of the device of Figure 14 in which a circuit is fabricated in the flat on a flexible polyimide substrate 2 that has been metallised on both faces. Three principal components are bonded onto this substrate namely a thin rectangular plate of piezo-ceramic material 3, two integrated circuit chips 4 and a multi-conductor cable that is not shown but which is bonded onto the interconnect bond pads 27. The thin rectangular piece of piezo-ceramic 3 (typically PZT)is precision diced into thirty two transducer elements. The circuit is shown with a certain profile 29

that has been selected with the final wrapped diameter in mind. Also shown on the circuit is a stress-relief slot 22 that aids the wrapping process.

Figure 16 is a cross-sectional view of the multiplexer arrangement of Figure 14. The folded polyimide substrate 2 with fine-pitch circuitry defined on it is shown enclosing two multiplexer chips 4a and 4b. The diagram shows that if the multiplexers are designed with typical widths of approximately 0.260 mm, the entire sensor fits into the dimensions of a 0.014 inch or 1 French guidewire. The chips are flip-chip-bonded onto bond pads by reflowing solder bumps 31 that are positioned on contact pads located on the chips. In this wrapped design, the two multiplexer chips are positioned back-to-back in order to fit within the 0.014 inch diameter and may be attached to each other through the use of a suitable adhesive.

Figures 17 and 18

These figures illustrate five possible constructions for the body of the catheter to the distal end of which the arrangement shown in Figure 14 is mounted.

Referring to Figure 17, a polyimide tube 32 with or without an external winding, which acts as a ground return, having a 1 French outer diameter contains within it three monofilaments 33 each consisting of a central copper conductor 34 (the external winding would act as a fourth conductor) with an outer dielectric jacket 35 which could be of low dielectric loss fluoropolymer. In order to maintain suitable torsional rigidity and stiffness three thin wires 36 that could be of a copper-alloy type are positioned within the remaining spaces.

Referring to Figure 18 the body comprises a stainless steel tube 37 having a 1 French outer diameter. The tube 37 contains three monofilaments 33 each consisting of a central copper conductor 34 with an outer dielectric jacket 35 which could be of a low dielectric loss fluoropolymer.

Figures 19 to 21

Referring to Figures 19 and 20 these illustrate possible body constructions which employ a steel-wire counterwinding 38.to add torsional rigidity to the assembly. In the arrangement of Figure 19 there are four monofilament electrical conductors 39 symmetrically disposed around a central mandrel 40.

In the arrangement of Figure 20 there are again four monofilament electrical conductors 39 but instead of the mandrel 40 there is an external tube 42 made of polyimide which contains the conductors and is reinforced, in terms of torsional rigidity, by the steel-wire counterwinding 38. These four monofilaments (electrical conductors 39) are configured into two twisted-pairs in order to aid in noise shielding.

Figure 21 illustrates a variation on the constructions of Figures 19 and 20 in that the separate steel-wire counterwinding 38 is replaced by a functionally equivalent spiral winding 43 which is formed integrally with the wall of a thin walled stainless-steel tube 44 that is centreless ground. In order to increase the flexibility of the tube 44 it is

provided with recesses or apertures 45 in its wall, having shapes and/or orientations which will promote flexibility whilst allowing the tube to retain its torsional rigidity. The spiral winding 43 may be filled with a suitable resin 46 to provide greater flexibility within the tip region of the catheter. Both the apertures/recesses 45 and the spiral winding 43 may be created, for example, by using a laser or through chemical means such as etching.

Figures 22 and 23

These figures illustrate what is in effect an electrical plug arrangement mounted at the proximal end of the catheter to enable it to be plugged into the external electrical/electronic equipment. The problem is that if a conventional electrical plug were used it would have too large an external diameter and prevent catheters being slid over the catheter from its proximal end.

With the arrangement illustrated the outside diameter of the plug arrangement is 1 French. Each one of the four conductors 39 extending through the length of the catheter has one conducting former 47 assigned to it. The conducting formers 47 are separated from one another by insulating formers 48. Both types of former 47 and 48 have an external diameter of 1 French thus maintaining the 0.014 inch external diameter throughout the entire length of the catheter, thus permitting the interchange of the various device catheters that may be required. These would be slid onto, over and along the guide-wire catheter illustrated.

Figure 23 shows one of the conducting formers 47 in detail where the insulating jacket 35 of one interconnect 33 has been stripped to expose the bare conductor 34. Each former 47 has four holes 49 to accommodate the interconnects 33. In each case, the bare conductor 34 is inserted into its respective hole 49 and affixed within it using a suitable technique such as reflow soldering or a conductive adhesive.

Because of the axial separations of the conducting formers 47 each of the four interconnects has to be a different length to enable it to be similarly inserted through its own insulating former 48 and into its own associated conducting former 47. The torsional counter winding 38 is suitably terminated before the first conducting former 47.

Suitable adhesives are used to pot the final assembly of the four electrically separated conducting formers 47 to form a connector which is adapted to plug into a stand-alone external system for further processing of the echo signals into an image.

CLAIMS

1) A catheter having both an ultrasonic transducer array and an inflatable balloon mounted on the catheter at or near its distal end.

2) A catheter as claimed in Claim 1 in which the array has a multiplexing arrangement associated with it and also mounted on the catheter at or near its distal end.

3) A catheter as claimed in Claim 1 or 2 in which the transducer array is located distal to the balloon, such that the diameter of the array is smaller than the balloon.

4) A catheter as claimed in Claim 2 in which the transducer array is located distal to the balloon such that the balloon covers the multiplexer section of the array thus allowing the distal end of the balloon to be closer to the array.

5) A catheter as claimed in Claim 1 or 2 in which the transducer array or the transducer array and the multiplexer arrangement respectively are carried on the outside of an inner catheter body which is located within a catheter outer body, the inner catheter body terminating at its proximal end in an aperture in the wall of the outer body whereby the catheter may be slid over and along a guide wire the distal end of which would lie substantially coaxially with the inner body and the distal end of the outer body.

6) A catheter as claimed in Claim 5 in which there is a reinforcing tube located within the outer body a part of which tube is located adjacent to the proximal end of the inner body

where it meets the said aperture in order to both reinforce the inner body at that point and also act as a conduit for the introduction of fluid into the balloon to support the latter.

7) A catheter as claimed in Claim 6 in which the distal end of the reinforcing tube is tapered.

8) A catheter as claimed in Claim 6 or 7 in which a fluid chamber is formed between the outside of the inner body and the inside of the outer body, the distal end of the reinforcing tube connecting with the said chamber through a fluid tight seal to enable fluid to be introduced into said chamber through the reinforcing tube.

9) A catheter as claimed in Claim 8 in which the outer body has one or more apertures in its wall whereby liquid in said chamber can flow into the balloon which is carried by and secured to the outside of the outer body.

10) A catheter as claimed in any previous claim in which the balloon comprises an elastometric envelope of substantially elongated configuration which in its uninflated condition is folded around the said outer body so that the introduction of the fluid causes the balloon material to unfold and adopt an inflated configuration.

11) A sheath catheter which comprises a cylindrical sheath, adapted to have a separate device catheter inserted through the lumen of the sheath, a substantially cylindrical ultrasonic transducer array and associated multiplexer arrangement being located within the said sheath and substantially co-axial therewith.

12) A sheath catheter as claimed in Claim 11 also including a tubular support located coaxially in the said sheath catheter and within said substantially cylindrical ultrasonic transducer array and associated multiplexer arrangement and being positioned and dimensioned to act as a support for the multiplexer arrangement.

13) A sheath catheter as claimed in Claim 11 or 12 and having a multiplexer protecting sheath located radially outwardly of the substantially cylindrical multiplexer arrangement.

14) A sheath catheter as claimed in any one of Claims 11 to 13 in which the wall of the catheter has formed therein a plurality of cross-sectioned lumens adapted to accomodate the same plurality of ribbon electrical conductors for transmitting and receiving electrical signals to and from the said transducer array and associated multiplexer arrangement.

15) A catheter which comprises a guide wire having an ultrasound transducer array mounted on its distal end and electrically conducting means between the said array and the proximal end of the guide wire whereby electrical signals may be transmitted to and received from the said array, the outside diameter of the catheter throughout its length being equal to or less than 1 French.

16) A catheter which comprises a guide wire having an ultrasonics transducer array mounted on its distal end and electrically conducting means between said array and the proximal end of the guide wire whereby electrical signals may be transmitted to and received from the said array, a multiplexer arrangement now being located at the distal end of the

guide wire and comprising two integrated circuits positioned back-to-back with respect to one another.

17) A catheter as claimed in Claim 16 in which the transducer array is of cylindrical configuration, the cylinder being filled with acoustic backing layer material

18) A catheter as claimed in Claim 16 or 17 in which the body of the catheter is provided with a torsional reinforcing winding.

19) A catheter as claimed in Claim 18 in which the winding is in the form of a separate element.

20) A catheter as claimed in Claim 18 in which the winding is found as an integral part of the catheter body.

21) A catheter as claimed in any of Claims 18 to 20 in which the body is rendered more flexible by having apertures or recesses formed in its wall.

22) A catheter as claimed in any one of Claims 16 to 21 in which the transducer array has a plurality of electrical cable connections extending substantially axially therefrom towards the proximal end of the catheter, there being a same plurality each of disc-like electrically insulating and electrically conducting formers respectively, located in line and proximally of the said cables, each said former having a plurality of apertures therethrough to accomodate at

least one of the said cables and each said cable having its central conductor electrically connected to a unique one of said electrically conducting formers.

23) A catheter as claimed in any previous claim in which there is a cylindrically tapered tip of relatively soft material formed on said distal end in order to facilitate the insertion of the catheter into a patient's artery.

24) A catheter as claimed in any previous claim in which the ultrasonic transducer array and associated multiplexer arrangement are initially formed in the flat and then wrapped into a cylinder for insertion into the distal end of the outer body of the catheter.

25) A catheter substantially as hereinfore described with reference to and as shown in Figures 1 to 3 of the accompanying drawings.

26) A catheter substantially as hereinfore described with reference to and as shown in Figures 9 to 13 of the accompanying drawings.

27) A catheter substantially as hereinfore described with reference to and as shown in Figures 14 to 23 of the accompanying drawings.

The Patent Office

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Claims searched: 1-10 & 23-25 **Date of search:** 25 February 1997

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Databases searched:

UK Patent Office collections, including GB, EP, WO & US patent specifications, in:

UK Cl (Ed.O): A5R (REKX, RGEC)

Int Cl (Ed.6): A61B 8/12, 17/22, 17/32, 17/36, A61N 7/00

Other: ONLINE: WPI

Documents considered to be relevant:

Category	Identity of document and relevant passage		Relevant to claims
X	WO 94/17734 A1	(ENDOSONICS) page 13 line 14-30 & figure 1	1,3 & 24
X	WO 94/07418 A1	(CARDIOVASCULAR IMAGING) page 4 line 26 - page 5 line 16	1,5 & 23
X	WO 92/11809 A1	(ENDOSONICS) page 11 line 8-page 12 line 2, page 17 line 11-19, figures 2a & 6a	1,3 & 5
X	WO 91/14401 A1	(CARDIOVASCULAR IMAGING) page 10 line 4-8 & figure 3	1 & 3
X	US 5279546	(MISCHE et al) column 4 line 31-34, column 5 line 16-22, figure 2 & 3	1,3
X	US 4856529	(SEGAL) column 3 line 52-68 & figure 3	1, 3 & 5

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